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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,410	06/23/2003	Joseph P. Desmond	BSCU-039/00US 027060-2227	7691
22903 7590 06/22/2009 COOLEY GODWARD KRONISH LLP ATTN: PATENT GROUP Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001			EXAMINER SZPIRA, JULIE ANN	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 06/22/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/601,410	Applicant(s) DESMOND, JOSEPH P.	
	Examiner JULIE A. SZPIRA	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 17-23, 27-29 and 32-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17-23, 27-29 and 32-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed 2/23/2009. Claims 1-10, 17-23, 27-29 and 32-45 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-6, 8-10, 17, 27 and 34-36** are rejected under 35 U.S.C. 102(b) as being anticipated by **Peterson (US 2001/0029353)**.

Regarding claims 1-5, 8-10, 27 and 34-36, Peterson discloses a first hollow member (112) with an inner diameter greater than that of the outer diameter of a second hollow member (115), which are cylinders (Figure 1a) comprising a semi-rigid plastic material (paragraph 33) and capable of accepting a medical instrument there through, with the second hollow member being movable coupled to the first hollow member (paragraph 27) and a wedge (132) having a first configuration (unlocked) and a second configuration (locked), the wedge being disposed apart from the second hollow member when the wedge is in the first configuration, the second hollow member being configured to move with respect to the first hollow member along a longitudinal axis defined by the first hollow member when the wedge is in the first configuration, the wedge being in contact with the second hollow member when the wedge is in the second configuration, the second hollow member being unable to move with respect to

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the first hollow member along the longitudinal axis defined by the first hollow member when the wedge is in the second configuration (paragraph 27). The second hollow member has a beveled (chamfered) edge that is capable of facilitating insertion into the body (Figure 1a). The first and second hollow members are in substantially fluid tight communication with one another with the combined length being longer than that of the first member alone (Figure 1a).

The wedge is configured to move within the first hollow member (wedge fits in portion 112a, and moves between a locked and unlocked configuration), and the wedge is disposed apart from the first hollow member when the wedge is in the first configuration (Figure 1a; paragraph 27).

Regarding claim 6, Peterson discloses the invention substantially as claimed above, but does not disclose the medical instrument being a catheter. However, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

Regarding claim 17, Peterson discloses the first hollow member has an interior surface that overlaps and is in frictional communication with a portion of an exterior surface of the proximal end of the second hollow member (paragraph 27).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Peterson (US 2001/0029353)**.

Regarding claim 7, Peterson discloses the invention substantially as claimed above and the second hollow member having a beveled edge, but fails to disclose the first hollow member having a beveled edge to facilitate insertion into the body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the first hollow member have a beveled edge like the second hollow member has, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

6. **Claim 18** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Peterson (US 2001/0029353)** in view of **Ash et al. (US 4,498,902)**.

Regarding claim 18, Peterson discloses the invention substantially as claimed above, but fails to disclose a longitudinal slot in the second hollow member.

However, Ash et al. teaches a hollow member with a longitudinal slot (12) along its length to allow the member to radially deform (column 2, lines 62-68).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a longitudinal slot to allow the member to have a change in diameter when the member needs to fit within a smaller diameter space than it is generally designed to fit within. Also, by allowing the device to achieve a smaller diameter, the outward radial force the second hollow member will exert on the first hollow member will create a stronger coefficient of friction and help to more securely connect the two hollow members (column 3, lines 11-15).

7. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Peterson (US 2001/0029353)** in view of **Arramon et al. (US 6,875,219)**.

Regarding claims 20 and 21, Peterson discloses the invention substantially as claimed above, but fails to disclose a radio opaque marking.

However, Arramon et al. teaches a radiopaque marker (104; column 9, lines 26-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a radiopaque marker to allow for the device to be visualized with an imaging device during a surgical procedure (column 9, lines 33-39).

8. **Claims 19, 22, 23 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Peterson (US 2001/0029353)** in view of **Stouder (WO 98/36785)**.

Regarding claim 19 and 28, Peterson discloses the invention substantially as claimed above, but fails to disclose an elastomeric ring.

Stouder discloses an elastomeric member (o-ring, 40) disposed between the distal end of the first member and the proximal end of the second end (page 9, lines 31-35).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include an elastomeric ring to prevent passage of gases or liquids between the two members (page 9, lines 31-35).

Regarding claims 22 and 23, Peterson discloses the invention substantially as claimed above, but fails to disclose a fastener and retaining slot.

Stouder discloses the device having a fastener (16) at the proximal end of the first hollow member with a retaining slot (20) to provide an interference fit for securing the guidewire device (page 8, lines 29-34).

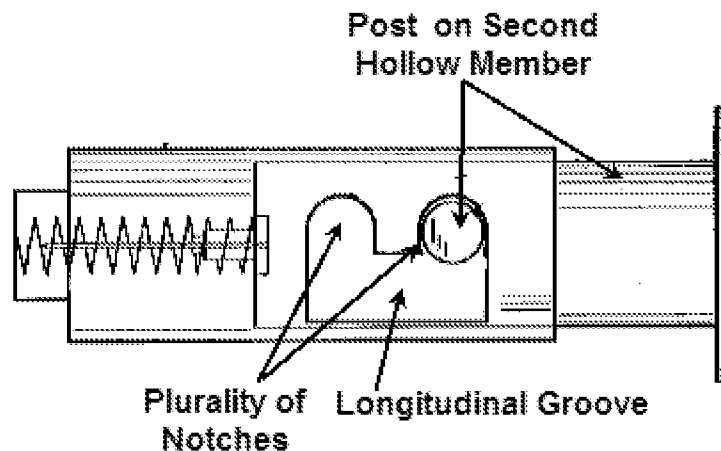
It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a fastener and retaining slot to accommodate instruments (guidewires) to be used with the device (page 8, lines 29-34).

9. **Claims 29, 32 and 37-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Peterson (US 2001/0029353)** in view of **Best Jr. et al (US 5,695,475)**.

Regarding claims 29, 32 and 37-40, Peterson discloses a first hollow member (116), a second hollow member (112) in slidable adjustable communication with the first member to adjust the overall length and sized to accept a medical instrument (Figure 1a). Peterson teaches a notch and detent system (paragraph 37), but fails to disclose a post and groove system.

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However, Best Jr. et al. teaches two hollow members with a post and groove locking adjustment mechanism. The first member has a longitudinal groove with a plurality of notches with an axis non-parallel to the longitudinal axis and the second member having a post configured to be disposed within the groove and slide along the groove into the notches as the device is adjusted (See Figure Below; column 3, lines 41-53). The device is in a locked configuration when the post is disposed within the notches.



It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a post and groove adjustment mechanism instead of a notch and detent mechanism to allow for the length of the device to be adjusted more easily by twisting and then axially sliding the members with respect to each other, as well as allowing the device to have multiple locking locations (column 2, lines 51-58),

10. **Claims 33 and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Peterson (US 2001/0029353)** in view of **Best Jr. et al. (US 5,695,475)**.

Regarding claim 33, Peterson in view of Best Jr. et al. discloses the invention substantially as claimed above but fails to disclose the first hollow member having a flange on the proximal end.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the first hollow member have a flange similar to that disclosed by element 112a, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70. Also, it would allow the device to be gripped easier at a position closer to the body which would allow for the device to be better manipulated during the procedure.

Regarding claim 41, Peterson in view of Best Jr. et al. discloses the invention substantially as claimed above but fails to disclose the second hollow member having an end face defining a plane non-orthogonal to a longitudinal axis.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second hollow member have a end face non-orthogonal to the longitudinal axis, similar to the end face of element 115, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70. Also, it would allow the end face to more easily enter another hollow member or a body cavity.

11. **Claims 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Peterson (US 2001/0029353)** in view of **Best Jr. et al (US 5,695,475)** further in view of **Arramon et al. (US 6,875,219)**.

Regarding claims 42 and 43, Peterson in view of Best Jr. et al. discloses the invention substantially as claimed above, but fails to disclose a radio opaque marking.

However, Arramon et al. teaches a radiopaque marker (104; column 9, lines 26-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a radiopaque marker to allow for the device to be visualized with an imaging device during a surgical procedure (column 9, lines 33-39).

12. **Claims 44 and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Peterson (US 2001/0029353)** in view of **Best Jr. et al (US 5,695,475)** further in view of **Stouder (WO 98/36785)**.

Regarding claims 44 and 45, Peterson in view of Best Jr. et al. discloses the invention substantially as claimed above, but fails to disclose a fastener and retaining slot.

Stouder discloses the device having a fastener (16) at the proximal end of the first hollow member with a retaining slot (20) to provide an interference fit for securing the guidewire device (page 8, lines 29-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a fastener and retaining slot to accommodate instruments (guidewires) to be used with the device (page 8, lines 29-34).

Response to Arguments

13. Applicant's arguments with respect to claims 1 and 29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/19/09